IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY, GENEOHM SCIENCES CANADA, INC. and HANDYLAB, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-1126 (LPS)
NEUMODX MOLECULAR, INC.,	)	
Defendant.	)	

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS NEUMODX'S COUNTERCLAIMS FOR NON-INFRINGEMENT AND INEQUITABLE CONDUCT AND TO STRIKE NEUMODX'S AFFIRMATIVE DEFENSE OF INEQUITABLE CONDUCT

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September 13, 2019

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I. NATURE AND STAGE OF THE PROCEEDINGS

In 2009, Plaintiffs Becton, Dickinson and Company and GeneOhm Science Canada, Inc. (collectively "BD"), acquired Plaintiff HandyLab, Inc. ("HandyLab"), after recognizing the potential of the emerging technologies being developed by HandyLab for use in bench-top devices for fast and early detection of disease. As part of that deal, BD gained an exclusive license to HandyLab's patents, including the Asserted Patents. *See* D.I. 1 ¶¶ 2, 10-11.[1] At the time, HandyLab's then-CEO Jeff Williams praised the "exclusive collaboration" with BD as "an important step in expanding the utility" of HandyLab's systems. D.I. 1, Ex. 7. Moreover, Williams said, the deal was "a good outcome for [HandyLab's] shareholders, [its] employees and for [its] customers." D.I. 1, Ex. 8. True to its word, and after having paid a substantial sum to acquire HandyLab's patented technology, BD continued to develop HandyLab's system with its own know-how and expertise. Ultimately BD used the patented technology to launch a successful next-generation molecular diagnostics platform, the BD MAX™ system. *See* D.I. 1 ¶¶ 12.[2]

In 2012, Williams founded a company called "Molecular Systems Corp.," which subsequently became Defendant NeuMoDx Molecular, Inc. ("NeuMoDx"). *Id.* ¶ 13. Sundaresh Brahmasandra, another co-founder of HandyLab who had subsequently taken the position of Vice President of R&D Assay Development at BD, later joined NeuMoDx. *Id.* The two HandyLab founders took the same patented technologies that they had sold and exclusively licensed to BD, and used them to develop NeuMoDx's own line of molecular

[1] The "Asserted Patents" are U.S. Patent Nos. 8,273,308; 8,703,609; 7,998,708; 8,323,900; 8,415,103; and 8,709,787. D.I. 1 ¶ 2.

[2] "Molecular diagnostics" is term used to describe a family of techniques used to analyze biological markers in an individual's genetic code and to analyze how their cells express their genes. *See* "Molecular Diagnostics," *ScienceDirect*, available at https://www.sciencedirect.com/topics/medicine-and-dentistry/molecular-diagnostics (last accessed Sept. 13, 2019). These techniques are used to "identify or confirm genetic variants associated with diseases or that can serve as surrogate markers of disease." *Id.* (citation omitted).

diagnostics products. Because NeuMoDx's products unlawfully infringe BD's patents, BD filed this action against NeuMoDx on June 18, 2019. D.I. 1.

NeuMoDx filed its answer and counterclaims on August 9, 2019. D.I. 8. As its First Count, NeuMoDx counterclaims for a declaratory judgment of non-infringement, in support of which NeuMoDx conclusorily asserts no more than: "NeuMoDx's Accused Molecular Diagnostic Products do not infringe any claims of the '308, '069, '708, '900, '103, and '787 patents, either directly or indirectly, because it does not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of [those] patents." D.I. 8 at 14-15. As its Third Count, NeuMoDx asserts a counterclaim for inequitable conduct based *solely* on a boilerplate remark by the prosecuting attorney made during the prosecution of one of the Asserted Patents, i.e., U.S. Patent No. 7,998,708. D.I. 8 at 17-20. NeuMoDx incorporates the same inequitable conduct allegation in its Third Affirmative Defense. D.I. 8 at 9.

Plaintiffs hereby move to dismiss NeuMoDx's non-infringement and inequitable conduct counterclaims under Federal Rule of Civil Procedure 12(b)(6), and also move to strike NeuMoDx's affirmative defense of unenforceability based on inequitable conduct under Federal Rule of Civil Procedure 12(f).

II. SUMMARY OF ARGUMENT

1. NeuMoDx's counterclaim for a declaratory judgment of non-infringement fails to satisfy the *Twombly/Iqbal* standard because it is wholly conclusory and does not plead any specific facts, much less facts from which non-infringement can plausibly be inferred.

2. NeuMoDx's inequitable conduct allegations are fatally deficient and should be dismissed. NeuMoDx alleges that BD committed inequitable conduct based solely on a prosecuting attorney's boilerplate remarks characterizing various proposed claim amendments. That type of attorney argument simply cannot constitute a factual assertion

giving rise to a material misrepresentation as a matter of law, particularly where there was no failure to disclose any factual information, nothing was hidden from the Patent Examiner, the claim amendments were before the Examiner, and the Examiner was free to reach his own determination about the meaning and import of those amendments.

3. Even if attorney argument could theoretically constitute a factual assertion giving rise to a material misstatement (which it cannot), NeuMoDx has failed to plead materiality with particularity, and it has also not pled facts from which the Court may reasonably infer that BD acted with the requisite knowledge and intent. In short, NeuMoDx's inequitable conduct allegations fail at every level.

III. BACKGROUND

This patent infringement dispute arises from NeuMoDx's use and marketing HandyLab's patented technologies that were previously sold to BD, even though NeuMoDx's owners and officers had full knowledge of the patents and were in fact the very ones who transferred those technologies to BD (for a substantial sum) in the first place. D.I. 1 ¶¶ 10-13. Among the Asserted Patents is the '708 patent, which is titled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" and issued on August 16, 2011 to named inventors Kalyan Handique, Sundaresh Brahmasandra, Karthik Ganesan, and Jeff Williams. D.I. 1, Ex. 3.

A. The '708 Patent Claims Were Amended During Prosecution, And The Prosecuting Attorney Explained Those Amendments In Related Remarks

On March 17, 2010, during the prosecution of the '708 patent, BD amended the claims. A true and correct copy of the March 17, 2010 Amendment and Response to Office

Action is attached as Exhibit 1.[3] The amendments changed the language of both of the pending independent claims and five of the 31 pending dependent claims. The changes were clearly identified under the header "AMENDMENTS TO THE CLAIMS" and black-lined to show the addition of new words and the deletion of original material. For example, the amendment showed the following changes to claim 1:

> 1. (Currently Amended) An apparatus, comprising:
>
> a microfluidic cartridge comprising a plurality of PCR reaction zones;
>
> a receiving bay configured to receive the ~~a~~ microfluidic cartridge;
>
> a plurality of separately controllable heat sources, each heat source thermally coupled to one or more of the plurality of PCR reaction zones and ~~at least one heat source thermally coupled to the cartridge and~~ configured to carry out PCR on a ~~microdroplet of~~ polynucleotide-containing sample[[,]] in a ~~the~~ respective PCR reaction zone ~~cartridge~~;
>
> a detector configured to detect the presence of an amplification product in the respective PCR reaction zone ~~one or more polynucleotides in the sample~~; and
>
> a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources ~~regions of the microfluidic cartridge~~.

Ex. 1 at 6.

In particular, the prosecuting attorney *added* certain limitations that were not previously in the claims, namely the requirements for a "plurality of PCR reaction zones" and a "plurality of separately controllable heat sources, each heat source thermally coupled to one or more of the plurality of PCR reaction zones." *Id*. In addition to adding those limitations to the claims, the prosecuting attorney also amended the claims with respect to the description of the functionality of the "heat source[s]." The initial claims required "at least one heat source . . . configured to carry out PCR on a microdroplet of polynucleotide-containing

[3] In deciding a motion to dismiss, the Court may take judicial notice of a patent's prosecution history, which is a public record. *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014), *aff'd sub nom. Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).

sample in the cartridge," whereas the amended claims required "each [of the plurality of] heat source[s] . . . configured to carry out PCR on a polynucleotide-containing sample in a respective PCR reaction zone." *Id.*

In Remarks, which were set forth in the same 15-page document as the amendments and which immediately followed the black-lines showing the amendments, the prosecuting attorney included a substantive discussion of the amendments.

At the conclusion of that Remarks section, the prosecuting attorney also included the following boilerplate attorney argument:

> Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

Id. at 15.

B. NeuMoDx Conclusorily Alleges Non-Infringement And Attempts To Raise Inequitable Conduct Based On Attorney Argument

NeuMoDx's bare-bones counterclaim for a declaratory judgment of non-infringement does not provide a single factual allegation supporting the plausibility of its claim. Instead, NeuMoDx formulaically recites the legal standard for non-infringement by asserting that its products "do[] not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim." D.I. 8 at 14-15.

NeuModx also included inequitable conduct allegations in its answer and counterclaims. While NeuMoDx's allegations in that regard are extremely vague and conclusory, NeuMoDx appears to suggest that the boilerplate language at the conclusion of the Remarks section gives rise to inequitable conduct.

Specifically, NeuMoDx alleges that the prosecuting attorney "removed the 'microdroplet' limit from the claims, broadening the claim to carrying out PCR on any

polynucleotide sample, not just a microdroplet." D.I. 8 at 18-19. NeuMoDx does not claim that the claim amendment was prohibited, unsupported, or somehow surreptitious. Instead, NeuMoDx latches on to the prosecuting attorney's boilerplate argument (quoted above) as the exclusive source of the alleged inequitable conduct. NeuMoDx alleges, without any factual support, that the statement was "intentionally incorrect and affirmatively misleading" because, in NeuMoDx's opinion, the removal of "microdroplet" was "not made to increase claim readability, improve grammar, or reduce the time and effort to understand the scope of the claim language" but instead "was an intentional and purposeful broadening of the claim beyond the scope of the invention contemplated by the inventors." *Id.* at 19. Solely "[u]pon information and belief" NeuMoDx accuses the prosecuting attorney of "misleading representations . . . made with the intention of deceiving the USPTO." *Id.* What information NeuMoDx possesses, or the basis of its belief for levying that serious charge, NeuMoDx does not say. Neither does NeuMoDx identify the source for its "information and belief [that] but for BD's false representations, the Examiner would have conducted additional searching given the broader scope of the claim requiring only a sample, not a microdroplet." *Id.* at 20. That search, NeuMoDx hypothesizes, would have led the Examiner to U.S. Patent Nos. 6,509,186 ("Zou I") and 6,762,049 ("Zou II"), but again NeuMoDx gives no explanation of how and why those references would have altered the result.

IV. LEGAL STANDARD

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In deciding a motion to dismiss, the court should assume the veracity of the factual allegations but must reject conclusory allegations. *LEO Pharma A/S v. Actavis Labs. UT, Inc.*, C.A. No. 16-333-JFB-SRF, 2018 WL 1045816,

at *2 (D. Del. Feb. 26, 2018) (citing *Iqbal*, 556 U.S. at 675, 678). In addition, the Court need not accept "'a legal conclusion couched as a factual allegation.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555).

Federal Rule of Civil Procedure 8 requires that "[a] pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), so as to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (citation omitted). Thus, the Supreme Court has held that the Rule 8 pleading standard "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

Because a claim of unenforceability based on inequitable conduct is a litigation tactic with drastic and "far-reaching consequences," the Federal Circuit has held that the standard for establishing intent and materiality is high. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289-91 (Fed. Cir. 2011) (en banc). A claim of inequitable conduct requires the accused infringer "prove that the applicant [1] misrepresented or omitted material information [2] with the specific intent to deceive the PTO." *Id.* at 1287. Information is not material unless, "but-for" the misrepresentation or omission, "the PTO would not have allowed a claim." *Id.* at 1291. And in order to establish specific intent to deceive, an accused infringer "must prove by clear and convincing evidence that [1] the applicant knew of the reference, [2] knew that it was material, and [3] made a deliberate decision to withhold it." *Id.* at 1290. Accordingly, even in cases of gross negligence where the patent applicant "should have known" of the materiality of the statement, this high bar is *not* met. *Id.* at 1290. Furthermore, to prove specific intent to deceive, an infringer must establish that the specific intent is "the single most reasonable inference able to be drawn from the evidence," and the

evidence "must be sufficient to *require* a finding of deceitful intent in light of all the circumstances." *Id.* (quotations omitted). The specific intent and materiality requirement are distinct prongs, so "a district court may not infer intent solely from materiality." *Id.*

Whether in an affirmative defense or a counterclaim, "inequitable conduct . . . must be pled with particularity" according to Federal Rule of Civil Procedure 9(b).[4] *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003); *see also Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013). Under Rule 9(b), to sufficiently plead inequitable conduct, "the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). In addition, the pleadings must "allege sufficient underlying facts from which a court may reasonably infer that a party acted" with specific deceptive intent to deceive. *Id.* at 1327. Inequitable conduct claims may be rejected as a matter of law upon a motion to dismiss. *Senju Pharm.*, 921 F. Supp. 2d at 308 (granting motion to dismiss counterclaim and strike affirmative defense of inequitable conduct).

V. ARGUMENT

A. NeuMoDx's Non-Infringement Counterclaim Fails To Satisfy *Twombly/Iqbal*

Following the Supreme Court's command in *Twombly* that Rule 8 "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do," 550 U.S. at 555, courts in this District and elsewhere have faithfully applied that precedent to counterclaims for declaratory judgment of non-infringement. In *Princeton Digital Image Corp. v. Konami Digital Entertainment Inc.*, for example, this Court held that

[4] Federal Circuit law applies to the question of whether inequitable conduct has been pleaded with particularity under Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009).

"[t]he *Twombly*/*Iqbal* standard should apply here to all aspects of the Second Counterclaim" alleging "no direct infringement." C.A. No. 12-1461-LPS-CJB, 2017 WL 239326, at *5 (D. Del. Jan. 19, 2017), *report and recommendation adopted*, 2017 WL 1196642 (D. Del. Mar. 30, 2017); *accord PetEdge, Inc. v. Marketfleet Sourcing, Inc.*, No. 16-cv-12562-FDS, 2017 WL 2983086, at *3 (D. Mass. July 12, 2017) (holding that "where a defendant seeks to assert a viable counterclaim for non-infringement, it must do more than deny infringement; it must also plead sufficient facts to state a plausible claim for relief").

In *Princeton Digital*, this Court granted the motion to dismiss a counterclaim of no direct infringement, agreeing that it was "merely a formulaic recitation of the elements of the claim [of noninfringement], without any supporting facts or even any identification of the products that are alleged not to infringe." 2017 WL 239326, at *5. The dismissed counterclaim merely alleged:

> 28. The allegations of Paragraphs 1-27 of the Counterclaims are incorporated by reference as if fully set forth herein.
>
> 29. Harmonix and EA have not infringed and are not infringing, either directly or indirectly, nor have the[y] contributed to or induced infringement by others, of any valid claim of the '129 patent, either literally or under the doctrine of equivalents.
>
> 30. Accordingly, Harmonix and EA are entitled to a declaratory judgment that they have not infringed and do not infringe the '129 patent.

Id. This Court found that that counterclaim "contain[ed] no facts of any kind, let alone sufficient facts to make out a plausible claim." *Id.*; *see also PetEdge*, 2017 WL 2983086, at *3 (dismissing counterclaim that "'Marketfleet has not infringed any valid and enforceable claim of the '236 patent, either literally or under the doctrine of equivalents, willfully or otherwise,' without further support" because it was "nothing more than a denial of infringement" and "fail[ed] to allege any facts to state a plausible claim for non-infringement").

NeuMoDx's conclusory noninfringement counterclaim is similarly wholly lacking in facts to support a plausible claim of noninfringement. NeuMoDx simply asserts that the "Accused Molecular Diagnostic Products do not infringe any claims, . . . either directly or indirectly, because it does not include each and every element, either literally or by application of the doctrine of equivalents." D.I. 8 at 14. NeuMoDx's assertion is, at most, a "formulaic recitation of the elements" of non-infringement, and there are no facts supporting a plausible counterclaim. Because NeuMoDx's non-infringement counterclaim is devoid of *any* factual support, it must be dismissed under *Twombly/Iqbal*.

B. NeuMoDx's Theory Is Fundamentally Flawed Because The Relevant Statements Are Attorney Argument, Not Factual Misrepresentations.

NeuMoDx's inequitable conduct counterclaim is a house of cards that rests entirely on a single argument made by the '708 patent's prosecuting attorney in "Remarks" relating to and submitted alongside clearly black-lined claim amendments. D.I. 8 at 19. NeuMoDx alleges that the attorney Remarks supporting those amendments were intentionally misleading because they did not specifically address the removal of the term "microdroplet" and the removal of that term allegedly "was not made to increase claim readability, improve grammar, or reduce the time and effort to understand the scope of the claim language." D.I. 8, at 18-19. Instead, NeuMoDx asserts that the removal of the word "was an intentional and purposeful broadening of the claim beyond the scope of the invention contemplated by the inventors." *Id*. at 19. NeuMoDx further speculates, without alleging any factual basis, that but for the statement in the Remarks, the Examiner would have conducted additional prior art searching and found art now identified by NeuMoDx. *Id*. at 19-20. NeuMoDx does not dispute, however, that the black-lined amendment to claim 1 were clear and available to the Examiner to review himself.

The attorney remarks upon which NeuMoDx builds its counterclaim *cannot*, as a matter of law, support a claim or defense of inequitable conduct because they are simply

attorney argument and do not qualify as misrepresentations to the Examiner. NeuMoDx's counterclaim therefore must fall under Rule 12(b)(6), and NeuMoDx's affirmative defense, which incorporates the counterclaim by reference, should also be struck under Rule 12(f).

The Federal Circuit has repeatedly rejected attempts to derive claims of inequitable conduct from statements made in the "routine back and forth between examiner and applicant." *See Rothman v. Target Corp.*, 556 F.3d 1310, 1329 (Fed. Cir. 2009). That precedent recognizes the important need for a prosecuting attorney—as with any attorney—to be able to freely "present argument in favor of patentability without fear of committing inequitable conduct." *Id*. at 1328-29. Accordingly, the Federal Circuit has treated attorney argument as "argument," rather than as representations of fact. Only the latter can form the basis for allegations of affirmative misrepresentation. For example, in *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000), the Federal Circuit reversed a bench trial determination of inequitable conduct where "the inventors merely advocated a particular interpretation of the teachings of [a prior art] article and the level of skill in the art, which the Examiner was free to accept or reject. This argument did not contain any factual assertions that could give rise to a finding of misrepresentation." *See also Masimo Corp. v. Philips Elec. N. Am. Corp.*, C.A. No. 09-0080, 2015 WL 2406061, at *12 (D. Del. May 18, 2015) (rejecting inequitable conduct claim based on prosecuting attorney's "advocacy of a claim construction position" because they "were *arguments*, not factual statements" or misrepresentations); *Cellectis S.A. v. Precision Biosciences*, 883 F. Supp. 2d 526, 535 (D. Del. 2012) (no inequitable conduct where "both examiners were free to credit or discount [applicants'] characterizations of [the prior art] in view of their own readings").

In particular, the Federal Circuit's decision in *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363 (Fed. Cir. 2008), compels dismissal of NeuMoDx's counterclaim. In *Innogenetics*, the applicant identified a prior art reference to the European

Patent Office as the closest prior art. *Id.* at 1378. During the prosecution of the U.S. application, the U.S. patent attorney included the same prior art on a list of prior art references but argued those references "do not relate to the invention." *Id.* at 1379. Not only did that statement clearly contradict the applicant's prior submission to the EPO, the U.S. patent attorney later admitted that he had not actually examined the reference and his statement was boilerplate. *Id.* Nonetheless, on facts stronger than NeuMoDx alleges here, the Federal Circuit held the attorney's statement was not a material misrepresentation because it was only "boilerplate language" that "amounted to mere attorney argument and our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art." *Id.* The Federal Circuit further explained that the reference was before the examiner, who was "was free to accept or reject the patentee's arguments." *Id.*; *see also Rothman*, 556 F.3d at 1329 (no inequitable conduct based on prosecuting attorney statements because the "examiner [has] the discretion to reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record").

This case illustrates the exact behavior that the en banc Federal Circuit warned against in *Therasense*, when it criticized the "overplayed" accusation of inequitable conduct "against [] reputable lawyers on the slenderest of grounds." 649 F.3d at 1289 (quotation marks and citation omitted). That is why NeuMoDx's approach must fail under Federal Circuit law, which shields attorney argument from frivolous charges of inequitable conduct. Here, as in *Innogenetics*, the prosecuting attorney was "free to advocate [his interpretation]" of the claim amendment to urge the Examiner to grant the amended claims. 512 F.3d at 1379. The Examiner had both the Remarks and the black-lined amendments before him, and therefore possessed full ability "to reject or accept [the] arguments based on [his] own conclusions regarding the prosecution record," *Rothman*, 556 F.3d at 1329, and evaluate the patentability

of the invention in view of the prior art. As a matter of law, the prosecuting attorney's statement was advocacy, not a "factual assertion[] that could give rise to a finding of misrepresentation." *Life Techs.*, 224 F.3d at 1326; *Masimo*, 2015 WL 2406061, at *12.

C. NeuMoDx's Inequitable Conduct Counterclaim Should Also Be Dismissed Because The Elements Of Inequitable Conduct Have Not Been Pled With Particularity.

NeuMoDx's counterclaim should also be dismissed because, although it has set forth a multistep materiality theory, NeuMoDx has failed to sufficiently plead either step with particularity. NeuMoDx's argument is not that the prosecuting attorney's statement about improving readability, grammar, and the time and effort needed to understand the claim—whether valid or not—would be material to patentability. Indeed, none of those targets are statutory bases for denying a patent. Instead, NeuMoDx theorizes that the statement somehow led the Examiner not to conduct prior art searches that would have led to material information. This materiality argument is based on two conclusory two assumptions: (1) the Examiner would have conducted more searches that would have uncovered different prior art, and (2) that prior art would have led to the Examiner rejecting the claim. D.I. 8, at ¶ 40.

In *Exergen*, the Federal Circuit explained that, in order to meet the Rule 9(b) particularity standard, a pleading must identify the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." 575 F.3d at 1327. NeuMoDx's allegations fail the *Exergen* standard in a myriad of ways. In the first place, NeuMoDx does not even satisfy the "who" requirement because the allegations generically assert actions by "BD," not "any specific individual [that had] the intent to deceive the PTO." *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 381 (D. Del. 2012). Second, NeuMoDx has failed to allege with particularity "what" other searches the Examiner would have run or "how" those searches would have found the prior art that it now cites. Instead, NeuMoDx relies on conclusory allegations that are contradicted by the only record evidence

it points to—the prosecution history—which suggests that the term "microdroplet" was not material to the Examiner's searches. For example, the Examiner conducted several prior art searches before the March 17, 2010 amendment. None of these searches were limited by the term "microdroplet." *See* Ex. 2 at 17-23. Nor were the Examiner's prior art searches conducted after the March 17, 2010 amendment limited by the term "microdroplet." *See* Ex. 3 at 19-21. Even so, the Examiner did not discover the prior art NeuMoDx alleges would have been found.

Similarly, NeuMoDx has not alleged with particularity why the claims of the '708 patent would not have been allowed in light of the prior art that it cites. Its pleading was required to "identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the 'what' and 'where' of the material omissions." *Exergen,* 575 F.3d at 1329. Rather than attempt to meet this burden, NeuMoDx has generally alleged that "the Examiner would have found a number of other prior art references that disclosed the elements of the claims of the '708 patent, but not a microdroplet, including, for example Zou I, U.S. Patent No. 6,509,186 and Zou II, U.S. Patent No. 6,762,049." D.I. 8 at 20. That allegation fails to explain "what" specifically is disclosed by Zou I and Zou II, and "where"—factual deficiencies that are "fatal" under Rule 9(b). *See Exergen*, 575 F.3d at 1330. These fatal defects also demonstrate that NeuMoDx likewise failed to plead sufficient facts supporting the "but-for materiality" required by *Therasense*. 649 F.3d at 1291.

NeuMoDx has also failed to plead definite facts to support its claim that there was a specific intent to deceive the PTO. It has alleged, at most: (1) BD's statement was incorrect and (2) that it "buried" the elimination of the microdroplet limitation with a number of other claim amendments. Even accepting NeuMoDx's allegations as true, a court could not reasonably infer that BD knew the statement was false and had a specific deceptive intent

because NeuMoDx has not provided a factual basis for its bald accusations that, "[u]pon information and belief, BD's false and misleading representations to the Patent Office were made with the intention of deceiving the USPTO." D.I. 8 at 19; *see Exergen*, 575 F.3d at 1330-31 (finding insufficient that "[d]eceptive intent . . . was pleaded solely on 'information and belief'" (brackets omitted)).

Moreover, even misstatements in attorney argument are immunized from accusations of deceptive intent where the information is openly provided to the Examiner, making clear the patentee's intent. *See Cornell Univ. v. Illumina, Inc.*, C.A. No. 10-433, 2017 WL 89165 (D. Del. Jan. 10, 2017) (holding it was not reasonable to infer from an "inartful" statement in a declaration that applicants intended to mislead the PTO where the actual language of the amendment the declaration supported made applicants' intention clear). Furthermore, as discussed above, the Federal Circuit has made clear that attorney argument characterizing the applicants' claims or the prior art does not constitute "factual assertions that could give rise to a finding of misrepresentation." *Life Techs.*, 224 F.3d at 1326; *accord Innogenetics*, 512 F.3d at 1379. The fact that, years later, NeuMoDx can pluck an argumentative characterization by an attorney out of the prosecution history and attribute to it some malicious purpose that is plainly inconsistent with the open amendment that it supports, does not provide a basis to infer deceptive intent.

NeuMoDx's suggestion that BD "buried" the elimination of the microdroplet limitation to hide it from the Examiner is likewise facially flawed. This Court has rejected the notion that "burying" a reference that is actually disclosed can constitute inequitable conduct. *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 358 (D. Del. 2009) ("An applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner."). Notably here, rather than hiding a statement or document among hundreds or thousands of pages of varying degrees of relevance, BD is alleged to have hidden a claim

amendment in a four-page, double-spaced document by clearly blacklining the language of claim 1 under the header: "AMENDMENTS TO THE CLAIMS." Because the claim amendment was actually cited to the Examiner, there can be no inequitable conduct found on the basis of "burying." *See Symbol Techs.*, 609 F. Supp. 2d at 358. Accordingly, NeuMoDx's Third Counterclaim should be dismissed.

Finally, NeuMoDx does not even attempt to address knowledge of materiality. *See Therasense*, 649 F.3d at 1290 (specific deceptive intent requires "kn[o]w[ledge] that it was material"). NeuMoDx fails to allege that any individual *knew that* the string of interdependent events NeuMoDx now hypothesizes would somehow come to pass and prevent a finding of unpatentability, much less include any facts allowing a court to infer that plausibly happened.

Like counterclaims, affirmative defenses of inequitable conduct both need to be plead with particularity under Rule 9(b), and accordingly they rise and fall together. *Senju Pharm.*, 921 F. Supp. 2d at 306. NeuMoDx's affirmative defense falls with its counterclaim and should, therefore, be struck under Rule 12(f).

VI. CONCLUSION

For all of the above reasons, the non-infringement and inequitable conduct counterclaims should be dismissed, and the inequitable conduct affirmative defense should be struck.

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September 13, 2019

CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 13, 2019, upon the following in the manner indicated:

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